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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/623,602      | 09/05/2000  | Anders Carlsson      | 13454NP             | 4856             |

7590 02/12/2003

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                 |
|------------------------------|-----------------|-----------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)    |
|                              | 09/623,602      | CARLSSON ET AL. |
| Examiner                     | Art Unit        |                 |
| Sharmila S. Gollamudi        | 1616            |                 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 04 December 2002.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-13 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

|   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

Request for Reconsideration received on December 4, 2002 is acknowledged.

Claims 1-13 are included in the prosecution of this application.

### ***Claim Rejections - 35 USC § 103***

**Rejection of claims 1-13 under 35 U.S.C. 103(a) as being unpatentable over US 6068860 in view of WO 95/20943 are maintained.**

### ***Response to Arguments***

Applicant argues that the intended use of the galactolipid material in the prior art is not the same as the present invention. Secondly, applicant argues that the reference is a gel containing 40% of galactolipids.

Applicant's arguments have been fully considered but they are not persuasive. In regards to the intended use, the examiner points to column 3, lines 45-48. Therefore the prolonged effect is inherent since the composition allows for the active agent to not only penetrate the skin but accumulation of the drug at high concentration at a given site provides for a prolonged local effect since a continued dose of the active is being supplied at the site. Although the art does not explicitly describe the prolonged effect, one of ordinary skill in the art would recognize this function as an implicit teaching. Also, the examiner points out that the instant claims do not provide a time period in which the activity is "prolonged". In regards to the secondary reference, in the absence of showing of unexpected results, it is the examiner's position that the prolonged effect is inherent since the instant composition and prior art compositions are similar in characteristics. The claiming of a new use, new function or unknown property that is

inherently present in the prior art does not necessarily make the claim patentable (Note MPEP 2112). It is the burden of the applicant to provide evidence that the "prolonged effect" does not naturally flow from the teaching of the prior art.

In regards to Carlsson teaching 40% of galactolipid, the examiner points out that claim 1 does not recite the amount of galactolipid in the composition. Secondly, Carlsson teaches 29% galactolipids in example 5. The secondary reference teaches the use of .01-50% galactolipid on page 3 and examples containing instant amounts. In regards to the argument that Carlsson only teaches gels, the examiner points out that the examples teach cream form and instant claims recite a topical cream or lotion. Further, the instant emulsion is emulsified to a cream form as also seen in Carlsson. In examples 5, the active is dissolved in water and mixed with the lipid material to form dispersion. Lastly, the secondary reference teaches an oil-in-water emulsion.

**Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlsson et al (6068860) in view of WO 95/20943 in further view of Horrobin (4444755).**

#### ***Response to Arguments***

Applicant argues the Carlsson references primarily. It is argued that Horrobin does not teach the instant linolenic acid.

Applicant's arguments have been fully considered but they are not persuasive. The arguments concerning Carlsson have been addressed above. The examiner points out that claim 12 is rejected in the Carlsson '860 in view of WO since WO teaches the use of linolenic acid on page 4. However, Horrobin is relied upon to disclose that not

only is the fatty acid used to treat skin disorder but also that primrose oil used by WO inherently contains said fatty acid.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Application/Control Number: 09/623,602  
Art Unit: 1616

Page 5

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG

*mg*  
February 6, 2003

*m g hartley*  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER